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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/771,931 | 02/04/2004 | Harry S. Courtney | 20638/1203595-US1 | 4163 |

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/771,931 | Applicant(s) COURTNEY, HARRY S. | |
| | Examiner Padmavathi v. Baskar | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/2/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 4- 8, 10, 12, 15, 17 and 19-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,9,11,13,14,16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/24/04 & 10/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Amendment

1. Applicant's response to restriction requirement filed on 5/2/06 is acknowledged.

Election/Restriction

2. Applicant's election Group 1, claims 1-4, 8-13, and 14-18 with traverse drawn compositions comprising one or more immunogenic portions from one or more Group A Streptococci serum opacity factor SOF2, SEQ.ID.NO: 1 is acknowledged.

Applicant indicated that in view of this species election, Applicant requests consideration of claims to additional species that, written in independent form or otherwise, include all limitations of a later allowed generic claim as provided by 37 CFR j 1.141. (s).

It is specifically noted, that a species election was not imposed. Each of the recited sequences was deemed patentably distinct from each other and applicants were required to elect a single product for examination on the merits. As such, examination of the single product will be restricted to the SEQ ID NO: 1 The examiner indicated that election is required of one composition or fusion protein or cocktail or a method of inducing an antibody immune response or method of treatment.

Applicant elected SOF2, SEQ.ID.NO: 1. However, applicant did not identify or inform the examiner what other peptides/epitopes are associated with the elected SEQ.ID.NO: 1.

Therefore, the examiner is examining the claims to the extent that they read on SEQ.ID.NO: 1.

When a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined, as a matter of right, in accordance with the provisions of MPEP 821.04.

The requirement is still deemed proper and is therefore made FINAL

Applicant timely traversed the restriction (election) requirement in the reply filed on 5/2/06.

Status of claims

3. Claims 1-40 are pending.

Claims 1-3, 9, 11, 13, 14, 16 and 18 are under examination. Applicant is advised to limit the claims to the elected invention, SEQ.ID.NO.1.

Claims 4, 8, 10, 12, 15 and 17 are withdrawn from the elected invention, as they are not drawn to the elected invention SEQ.ID.NO.1.

Claims 5-7, 19-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P § 821.03.

Priority

4. This application 10/771931 filed on 02/04/2004 claims Priority from Provisional Application 60/446,061, 02/05/2003 is acknowledged.

Information Disclosure Statement

5. The Information Disclosure Statement is filed on 5/24/04 and 10/25/05 are reviewed and a signed copy of the same is attached to this office action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3, 9, 11, 13, 14, 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said polypeptide" in line 3. There is insufficient antecedent basis for this limitation in the claim. However, does applicant intend to mean said composition?

Claims 11 and 16 are rejected as being vague because the claims are drawn to a fusion protein and cocktail, however, the scope of the claims is not different from each other.

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Claims 9 and 14 recite 103, 104etc. However, it is not clear whether these are SEQ.ID.NO or something else.

(Please note the applicant is advised to limit the claims to restricted SEQ.ID.NO: 1 in para#).

In claim 13 the abbreviations "R28, SPA, SFB1 etc" are used without definition upon their first appearance in the claims.

Claim Rejections - 35 USC 101

8. 35 U.S.C. 101 reads as Follows

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

9. Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The product, a protein as claimed, has the same characteristics and utility as that found in nature because the protein can be obtained from any source such as human body etc. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology "essentially purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v. H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 9,11,13, 14, 16 and 18 are rejected under 35 U.S.C. 102 as being

anticipated by Courtney et al *Mol Microbiol.* April 1999, Vol 32, No.1, pages 89-98.

(IDS 5/24/04, page 1,7th reference).

Claims are drawn to a composition comprising one or more immunogenic portions from one or more Group A streptococci serum opacity factors (SOF) and a biologically acceptable diluent wherein said polypeptide is capable of eliciting a protective immune response when administered in vivo to a mammal, wherein said Group A streptococci is *Streptococcus pyogenes*, wherein said SOF is *S. pyogenes* SOF2 (SEQ ID NO: 1). Claims are drawn to fusion protein and cocktail comprising SEQ.ID.NO: 1 and one or more immunogenic portions of a non-*S. pyogenes* SOF2, said nonSOF2 is *S. pyogenes* M protein, R28 protein, SPA, C5a peptidase, SFBI (also known as protein F1), and FBP54.

The prior art discloses a composition comprising Group A *S.pyogenes* serum opacity factor (SOF) in a biologically acceptable diluent PBS (see page 96, left column, first paragraph).

This composition comprises SOF2 and is 100% identical to the claimed SEQ.ID.NO: 1 (see

sequence alignment with the prior art type 2 factor) The composition comprises SOF2

comprising fusion protein and SOF49 (see page 91, under results and figure 1) and thus read

on the composition claims and fusion proteins as in 1-3, 9, 11, and 13. Since the composition

contains more than one immunogenic portion in polypeptide SEQ.ID.NO: 1, SOF2 it reads on

cocktail claims 14, 16 and 18. Rabbit antiserum raised against SOF2 (see page 96, left column, first paragraph) by injecting the composition containing SOF2 to said mammal and thus it reads

on the claim 1. Expression of sof is controlled by the positive regulator Mga that consists of M-related protein and C5a peptidase (see page 91, top left column) and thus meet the limitations of claims 11, 13, 16 and 18. The prior art anticipated the claimed invention.

12. Claims 1, 9 and 14 are rejected under 35 U.S.C. 102 (b) as being anticipated by

Kreikemeyer et al *Mol Microbiol.* 1995 Jul; 17(1): 137-45 ((IDS 5/24/04, page 2,11th reference).

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Claims have been discussed supra.

Kreikemeyer discloses a composition comprising fusion protein from *S.pyogenes* and said fusion protein is 113 KD protein, SfbII and GST (see page 144, under purification of fusion protein and generation of antibodies). This protein is 62.5% identical with the claimed SEQ.ID.NO: 1 (see the sequence alignment) comprising one or more immunogenic portions (see position 1-20, 980-100) as the serum raised against this protein inhibited the sfbII receptor. The composition given to mammal contains more than one polypeptide and thus reads on cocktail. Therefore, this composition reads on composition claim, fusion protein and cocktail comprising one or more polypeptides of SEQ.ID.NO: 1. The prior art anticipated the claimed invention.

Remarks

13. No claims are allowed.

Conclusion

14. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D


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